FEB - 8 2005

K043584

Summary of Safety and Effectiveness
Liquichek™ BNP Control

1.0 Submitter

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
Fax: (949) 598-1557

Contact Person

Suzanne S. Parsons
Regulatory Affairs Specialist
Telephone: (949) 598-1467

Date of Summary Preparation

December 21, 2004

2.0 Device Identification

Product Trade Name:	Liquichek BNP Control
Common Name:	Single (Specific) Analyte Controls, (Assayed and Unassayed)
Classifications:	Class I
Product Code:	JJX
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek™ Cardiac Markers Control LT
Bio-Rad Laboratories
Irvine, California

Docket Number: K040277

4.0 Description of Device

Liquichek BNP Control is prepared from human serum with added constituents of human and animal origin, preservatives and stabilizers. The control is provided in liquid form.

5.0 Statement of Intended Use

6.0 Liquichek BNP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the B-type Natriuretic Peptide (BNP).

The Liquichek BNP Control does not contain sodium azide as a preservative. It contains a broad-spectrum anti-microbial cocktail as a preservative where the concentration of any one ingredient is less than 0.1%. At this low level, these ingredients are not expected to cause a health hazard to the user. And thus, domestic and international regulations do not require this type of information on the vial or box label.

7.0 Comparison of the new device with the Predicate Device

Liquichek BNP Control claims substantial equivalence to the Liquichek™ Cardiac Markers Control LT currently in commercial distribution. The new Liquichek BNP Control is a 3 level product (Level 1, 2, and 3) and contains only BNP. The current product is a multi-analyte product and does not contain BNP.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Liquichek™ BNP Control (New Device)	Bio-Rad Liquichek™ Cardiac Markers Control LT (Predicate Device K040277)
Similarities		
Intended Use	Liquichek BNP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures B-type Natriuretic Peptide (BNP).	Liquichek Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Differences		
Storage (Unopened)	–20°C to -70°C Until expiration date	–20°C or colder Until expiration date
Open Vial Claim	20 days at 2-8°C	All analytes 10 days, NT-proBNP 4 days at 2-8°C
Analytes	Contains: B-type Natriuretic Peptide (BNP) Does not contain: CK-MB Isoenzyme Digitoxin Homocysteine Myoglobin N-terminal pro-B-type Natriuretic Peptide (NT-pro BNP) Troponin I Troponin T	Contains: CK-MB Isoenzyme Digitoxin Homocysteine Myoglobin N-terminal pro-B-type Natriuretic Peptide (NT-pro BNP) Troponin I Troponin T Does not contain B-type Natriuretic Peptide (BNP)

2.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ BNP Control. Product claims are as follows:

2.1 Open vial: All analytes will be stable for 20 days at 2 to 8°C.

2.2 Shelf Life: 2 years at -20°C to -70°C

2.3 Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 8 2005

Suzanne S. Parsons
Regulatory Affairs Specialist
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k043584
Trade/Device Name: Liquichek BNP Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: December 21, 2004
Received: December 28, 2004

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043584

Device Name: **Liquichek BNP Control**

Indications For Use: **Liquichek BNP Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for B-type Natriuretic Peptide (BNP).**

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K043584